

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 2001 General Assembly.

SENATE ENROLLED ACT No. 228

AN ACT to amend the Indiana Code concerning Medicaid and to make an appropriation.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 4-12-8-2, AS AMENDED BY P.L.291-2001, SECTION 70, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 2. (a) The Indiana prescription drug account is established within the Indiana tobacco master settlement agreement fund for the purpose of providing access to needed prescription drugs to ensure the health and welfare of Indiana's low-income senior citizens. The account consists of:

- (1) amounts to be distributed to the account from the Indiana tobacco master settlement agreement fund;
- (2) appropriations to the account from other sources; ~~and~~
- (3) **rebates:**

(A) required under 42 U.S.C. 1396r-8(a) for a Medicaid waiver under which a prescription drug program is established or implemented; or

(B) voluntarily negotiated under a prescription drug program that is established or implemented;

to provide access to prescription drugs for low income senior citizens; and

- (4) grants, gifts, and donations intended for deposit in the account.

(b) The account shall be administered by the budget agency. Expenses for administration and benefits under the Indiana prescription



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drug program established under IC 12-10-16 shall be paid from the account. Money in the account at the end of the state fiscal year does not revert to the state general fund **or the Indiana tobacco master settlement agreement fund** but **is annually appropriated and** remains available for expenditure **for a prescription drug program established or implemented to provide access to prescription drugs for low income senior citizens.**

(c) Money in the account may be used to match federal funds available under a Medicaid waiver under which a prescription drug program is established or implemented to provide access to prescription drugs for low income senior citizens.

SECTION 2. IC 4-23-27-7, AS ADDED BY P.L.273-1999, SECTION 162, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: Sec. 7. The board shall direct policy coordination of children's health programs by doing the following:

- (1) Developing a comprehensive policy in the following areas:
 - (A) Appropriate delivery systems of care.
 - (B) Enhanced access to care.
 - (C) The use of various program funding for maximum efficiency.
 - (D) The optimal provider participation in various programs.
 - (E) The potential for expanding health insurance coverage to other populations.
 - (F) Technology needs, including development of an electronic claim administration, payment, and data collection system that allows providers to have the following:
 - ⊕ (i) Point of service claims payments.
 - (ii) Instant claims adjudication.
 - (iii) Point of service health status information.
 - (iv) Claims related data for analysis.
 - (G) Appropriate organizational structure to implement health policy in the state.
- (2) Coordinating aspects of existing children's health programs, including the children's health insurance program, Medicaid managed care for children, first steps, and children's special health care services, in order to achieve a more seamless system easily accessible by participants and providers, specifically in the following areas:
 - (A) Identification of potential enrollees.
 - (B) Outreach.
 - (C) Eligibility criteria.
 - (D) Enrollment.



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- (E) Benefits and coverage issues.
- (F) Provider requirements.
- (G) Evaluation.
- (H) Procurement policies.
- (I) Information technology systems, including technology to coordinate payment for services provided through the children's health insurance program under IC 12-17.6 with:
 - ⊕ (i) services provided to children with special health needs; and
 - (ii) public health programs designed to protect all children.
- (3) Reviewing, analyzing, disseminating, and using data when making policy decisions.
- (4) Overseeing implementation of the children's health insurance program under IC 12-17.6, including:
 - (A) reviewing:
 - ⊕ (i) benefits provided by;
 - (ii) eligibility requirements for; and
 - (iii) each evaluation of;

the children's health insurance program on an annual basis in light of available funding; ~~and~~
 - (B) making recommendations for changes to the children's health insurance program to the office of the children's health insurance program established under IC 12-17.6-2-1; **and**
 - (C) studying benefits appropriate for children's mental health and addiction services.**

SECTION 3. IC 5-10-8-12 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: **Sec. 12. (a) As used in this section, "covered individual" means an individual who is covered under an employee health plan.**

(b) As used in this section, "employee health plan" means:

- (1) a self-insurance program established under section 7(b) of this chapter; or**
- (2) a contract with a prepaid health care delivery plan entered into under section 7(c) of this chapter;**

that provides a prescription drug benefit.

(c) The state personnel department may report to the drug utilization review board established by IC 12-15-35-19, not later than October 1 of each calendar year, the number of covered individuals who are:

- (1) less than eighteen (18) years of age; and**
- (2) prescribed a stimulant medication approved by the federal Food and Drug Administration for the treatment of attention**



deficit disorder or attention deficit hyperactivity disorder.

SECTION 4. IC 12-7-2-40.5 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 40.5. "Compendia", for purposes of IC 12-15-35 and **IC 12-15-35.5**, has the meaning set forth in IC 12-15-35-3.

SECTION 5. IC 12-7-2-48.5 IS ADDED TO THE INDIANA CODE AS A **NEW SECTION** TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 48.5. "**Covered outpatient drug**", for purposes of **IC 12-15-35**, has the meaning set forth in **IC 12-15-35-4.5**.

SECTION 6. IC 12-7-2-51.8 IS ADDED TO THE INDIANA CODE AS A **NEW SECTION** TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 51.8. "**Cross-indicated drug**", for purposes of **IC 12-15-35.5**, has the meaning set forth in **IC 12-15-35.5-2**.

SECTION 7. IC 12-7-2-178.5 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 178.5. "Single source drug" ~~for purposes of IC 12-15-35-35~~, has the meaning set forth in ~~IC 12-15-35-35(a)~~; **means an outpatient drug that is produced or distributed under an original new drug application approved by the federal Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.**

SECTION 8. IC 12-7-2-190.6 IS ADDED TO THE INDIANA CODE AS A **NEW SECTION** TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 190.6. "**Therapeutic classification**" or "**therapeutic category**", for purposes of **IC 12-15-35**, has the meaning set forth in **IC 12-15-35-17.5**.

SECTION 9. IC 12-7-2-196.5 IS ADDED TO THE INDIANA CODE AS A **NEW SECTION** TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 196.5. "**Unrestricted access**", for purposes of **IC 12-15-35.5**, has the meaning set forth in **IC 12-15-35.5-2.5**.

SECTION 10. IC 12-15-5-6 IS ADDED TO THE INDIANA CODE AS A **NEW SECTION** TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 6. **The office may not limit the number of brand name prescription drugs a recipient may receive under the program.**

SECTION 11. IC 12-15-12-14, AS ADDED BY P.L.291-2001, SECTION 160, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: Sec. 14. (a) This section applies to a Medicaid recipient: ~~who:~~

(1) **who** is determined by the office to be eligible for enrollment



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in a Medicaid managed care program; ~~and~~

(2) **whose Medicaid eligibility is not based on the individual's aged, blind, or disabled status; and**

(3) **who** resides in a county having a population of:

(A) more than ~~one hundred fifty thousand (150,000)~~ but less than ~~one hundred sixty thousand (160,000)~~; **one hundred eighty-two thousand seven hundred ninety (182,790) but less than two hundred thousand (200,000);**

(B) more than ~~one hundred sixty thousand (160,000)~~ but less than ~~two hundred thousand (200,000)~~; **one hundred seventy thousand (170,000) but less than one hundred eighty thousand (180,000);**

(C) more than two hundred thousand (200,000) but less than three hundred thousand (300,000);

(D) more than three hundred thousand (300,000) but less than four hundred thousand (400,000); or

(E) more than four hundred thousand (400,000) but less than seven hundred thousand (700,000).

(b) Not later than January 1, 2003, the office shall require a recipient described in subsection (a) to enroll in the risk-based managed care program.

(c) The office:

(1) shall apply to the United States Department of Health and Human Services for any approval necessary; and

(2) may adopt rules under IC 4-22-2;

to implement this section.

SECTION 12. IC 12-15-35-4.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 4.5. As used in this chapter, "covered outpatient drug" has the meaning set forth in 42 U.S.C. 1396r-8(k)(2).**

SECTION 13. IC 12-15-35-17.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 17.5. As used in this chapter, "therapeutic classification" or "therapeutic category" means a group of pharmacologic agents primarily characterized by a significant similarity of the biochemical or physiological mechanism by which these agents result in the intended clinical outcome.**

SECTION 14. IC 12-15-35-20.1, AS ADDED BY P.L.231-1999, SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 20.1. (a) Each board member **and each**

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therapeutics committee member shall fully disclose any potential conflicts of interest, financial or otherwise, relating to an issue that comes before the board **or committee** for recommendation or other action.

(b) A board member **or therapeutics committee member** may not vote on a recommendation or other action if the member or the member's employer has a conflict of interest, financial or otherwise, in the outcome of the vote.

(c) A board member **or therapeutics committee member** who may not vote on a recommendation or other action under subsection (b) may still participate in any discussions regarding the recommendation or other action.

SECTION 15. IC 12-15-35-20.5 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 20.5. (a) The therapeutics committee is established as a subcommittee of the board.**

(b) The chairperson of the board elected under section 25 of this chapter shall, with the approval of a majority of a quorum of the board, appoint the members of the therapeutics committee.

(c) The therapeutics committee is composed of the following members:

- (1) Five (5) physicians licensed under IC 25-22.5, including:**
 - (A) one (1) physician with expertise in the area of family practice;**
 - (B) one (1) physician with expertise in the area of pediatrics;**
 - (C) one (1) physician with expertise in the area of geriatrics;**
 - (D) one (1) physician with expertise in psychiatric medicine; and**
 - (E) one (1) physician with expertise in the area of internal medicine and who specializes in the treatment of diabetes.**
- (2) Two (2) pharmacists who are licensed under IC 25-26 and who have a doctor of pharmacy degree or an equivalent degree.**

(d) Not more than three (3) of the individuals appointed by the chairperson under subsection (b) to the therapeutics committee may also be members of the board.

(e) At least three (3) of the members described in subsection (c)(1) and appointed under subsection (b) must have at least three (3) years of recent experience in prescription drug formulary management, including therapeutic category review.



(f) A member of the therapeutics committee may not:

- (1) be employed by; or
- (2) contract with;

the state or a pharmaceutical manufacturer or labeler. However, this subsection does not apply to a physician or a pharmacist whose only contract with the state is a Medicaid provider agreement under IC 12-15-11 or a provider agreement under the children's health insurance program under IC 12-17.6.

(g) The term of a member of the therapeutics committee is three (3) years. A member may be reappointed to the committee upon the completion of the member's term.

(h) The expenses of the therapeutics committee shall be paid by the office.

(i) Each member of the therapeutics committee is entitled to the minimum salary per diem provided by IC 4-10-11-2.1(b). The member is also entitled to reimbursement for traveling expenses as provided under IC 4-13-1-4 and other expenses actually incurred in connection with the member's duties as provided in the state policies and procedures established by the Indiana department of administration and approved by the budget agency.

(j) The affirmative votes of a majority of a quorum of the therapeutics committee are required for the committee to take action on any measure. A quorum of the therapeutics committee consists of four (4) members.

(k) The therapeutics committee shall meet:

- (1) upon the call of the chairperson of the therapeutics committee; and
- (2) at least quarterly.

(l) The chairperson and the vice chairperson of the therapeutics committee:

- (1) each serve for a term of one (1) year; and
- (2) must be elected from the therapeutics committee's membership at the therapeutics committee's first meeting each calendar year.

(m) A meeting held by the therapeutics committee must be open to the public in accordance with IC 5-14-1.5. However, the therapeutics committee may meet in executive session only for the purpose of reviewing confidential or proprietary information.

SECTION 16. IC 12-15-35-26, AS AMENDED BY P.L.291-2001, SECTION 162, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 26. (a) The secretary shall provide additional staff to the board.



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(b) The secretary shall provide staff for the therapeutics committee.

SECTION 17. IC 12-15-35-28 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 28. **(a)** The board has the following duties:

- (1) The adoption of rules to carry out this chapter, in accordance with the provisions of IC 4-22-2 and subject to any office approval that is required by the federal Omnibus Budget Reconciliation Act of 1990 under Public Law 101-508 and its implementing regulations.
- (2) The implementation of a Medicaid retrospective and prospective DUR program as outlined in this chapter, including the approval of software programs to be used by the pharmacist for prospective DUR and recommendations concerning the provisions of the contractual agreement between the state and any other entity that will be processing and reviewing Medicaid drug claims and profiles for the DUR program under this chapter.
- (3) The development and application of the predetermined criteria and standards for appropriate prescribing to be used in retrospective and prospective DUR to ensure that such criteria and standards for appropriate prescribing are based on the compendia and developed with professional input with provisions for timely revisions and assessments as necessary.
- (4) The development, selection, application, and assessment of interventions for physicians, pharmacists, and patients that are educational and not punitive in nature.
- (5) The publication of an annual report that must be subject to public comment before issuance to the federal Department of Health and Human Services and to the Indiana legislative council by December 1 of each year.
- (6) The development of a working agreement for the board to clarify the areas of responsibility with related boards or agencies, including the following:
 - (A) The Indiana board of pharmacy.
 - (B) The medical licensing board of Indiana.
 - (C) The SURS staff.
- (7) The establishment of a grievance and appeals process for physicians or pharmacists under this chapter.
- (8) The publication and dissemination of educational information to physicians and pharmacists regarding the board and the DUR program, including information on the following:
 - (A) Identifying and reducing the frequency of patterns of

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fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and recipients.

(B) Potential or actual severe or adverse reactions to drugs.

(C) Therapeutic appropriateness.

(D) Overutilization or underutilization.

(E) Appropriate use of generic drugs.

(F) Therapeutic duplication.

(G) Drug-disease contraindications.

(H) Drug-drug interactions.

(I) Incorrect drug dosage and duration of drug treatment.

(J) Drug allergy interactions.

(K) Clinical abuse and misuse.

(9) The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the DUR program that identifies individual physicians, pharmacists, or recipients.

(10) The implementation of additional drug utilization review with respect to drugs dispensed to residents of nursing facilities shall not be required if the nursing facility is in compliance with the drug regimen procedures under 410 IAC 16.2-3-8 and 42 CFR 483.60.

(11) The research, development, and approval of a preferred drug list for:

(A) Medicaid's fee for service program;

(B) Medicaid's primary care case management program; and

(C) the primary care case management component of the children's health insurance program under IC 12-17.6; in consultation with the therapeutics committee.

(12) The approval of the review and maintenance of the preferred drug list at least two (2) times per year.

(13) The preparation and submission of a report concerning the preferred drug list at least two (2) times per year to the select joint commission on Medicaid oversight established by IC 2-5-26-3.

(14) The collection of data reflecting prescribing patterns related to treatment of children diagnosed with attention deficit disorder or attention deficit hyperactivity disorder.

(b) The board shall use the clinical expertise of the therapeutics committee in developing a preferred drug list. The board shall also

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consider expert testimony in the development of a preferred drug list.

(c) In researching and developing a preferred drug list under subsection (a)(11), the board shall do the following:

- (1) Use literature abstracting technology.
- (2) Use commonly accepted guidance principles of disease management.
- (3) Develop therapeutic classifications for the preferred drug list.
- (4) Give primary consideration to the clinical efficacy or appropriateness of a particular drug in treating a specific medical condition.
- (5) Include in any cost effectiveness considerations the cost implications of other components of the state's Medicaid program and other state funded programs.

(d) Prior authorization is required for coverage under a program described in subsection (a)(11) of a drug that is not included on the preferred drug list.

(e) The board shall determine whether to include a single source covered outpatient drug that is newly approved by the federal Food and Drug Administration on the preferred drug list not later than sixty (60) days after the date of the drug's approval. However, if the board determines that there is inadequate information about the drug available to the board to make a determination, the board may have an additional sixty (60) days to make a determination from the date that the board receives adequate information to perform the board's review. Prior authorization may not be automatically required for a single source drug that is newly approved by the federal Food and Drug Administration and that is:

- (1) in a therapeutic classification:
 - (A) that has not been reviewed by the board; and
 - (B) for which prior authorization is not required; or
- (2) the sole drug in a new therapeutic classification that has not been reviewed by the board.

(f) The board may not exclude a drug from the preferred drug list based solely on price.

(g) The following requirements apply to a preferred drug list developed under subsection (a)(11):

- (1) The office or the board may require prior authorization for a drug that is included on the preferred drug list under the following circumstances:

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- (A) To override a prospective drug utilization review alert.
 - (B) To permit reimbursement for a medically necessary brand name drug that is subject to generic substitution under IC 16-42-22-10.
 - (C) To prevent fraud, abuse, waste, overutilization, or inappropriate utilization.
 - (D) To permit implementation of a disease management program.
 - (E) To implement other initiatives permitted by state or federal law.
- (2) All drugs described in IC 12-15-35.5-3(b) must be included on the preferred drug list.
- (3) The office may add a new single source drug that has been approved by the federal Food and Drug Administration to the preferred drug list without prior approval from the board.
- (4) The board may add a new single source drug that has been approved by the federal Food and Drug Administration to the preferred drug list.
- (h) At least two (2) times each year, the board shall provide a report to the select joint commission on Medicaid oversight established by IC 2-5-26-3. The report must contain the following information:
- (1) The cost of administering the preferred drug list.
 - (2) Any increase in Medicaid physician, laboratory, or hospital costs or in other state funded programs as a result of the preferred drug list.
 - (3) The impact of the preferred drug list on the ability of a Medicaid recipient to obtain prescription drugs.
 - (4) The number of times prior authorization was requested, and the number of times prior authorization was:
 - (A) approved; and
 - (B) disapproved.
- (i) The board shall provide the first report required under subsection (h) not later than six (6) months after the board submits an initial preferred drug list to the office.
- SECTION 18. IC 12-15-35-28.5 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 28.5. The therapeutics committee established under section 20.5 of this chapter shall do the following:**
- (1) Advise and make recommendations to the board in the board's development and maintenance of a preferred drug list

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under section 28 of this chapter.

(2) Submit to the board a proposed preferred drug list that has been approved by a majority of a quorum of the therapeutics committee.

(3) Advise and make recommendations to the board in the board's review and maintenance of a preferred drug list.

SECTION 19. IC 12-15-35-28.7 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 28.7. (a) The board shall submit the initial approved preferred drug list to the office not later than August 1, 2002.

(b) Except as permitted under subsection (g), the office may not further restrict the status of a drug in the Medicaid program or the children's health insurance program until the board reviews a therapeutic classification and the office implements the therapeutic classification on the preferred drug list.

(c) The office shall provide advance notice to providers of the contents of the preferred drug list submitted by the board under subsection (a).

(d) Notwithstanding IC 12-15-13-6, the office shall implement any change in the preferred drug list not later than thirty (30) days after the date the board submits the amended list to the office.

(e) The office may not implement a preferred drug list or an amendment to the preferred drug list that has not been approved by the board.

(f) The office may not require prior authorization for a drug that is excluded from the preferred drug list unless the board has made the determinations required under section 35 of this chapter.

(g) The office may adopt rules under IC 4-22-2 necessary to carry out this chapter.

SECTION 20. IC 12-15-35-35, AS AMENDED BY P.L.231-1999, SECTION 6, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 35. (a) As used in this section, "single source drug" means a covered outpatient drug that is produced or distributed under an original new drug application approved by the federal Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(b) (a) Before the board develops a program to place a single source drug on prior approval, restrict the drug in its use, or establish a drug monitoring process or program to measure or restrict utilization of single source drugs other than in the SURS program, the board must

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meet the following conditions:

(1) Make a determination, after considering evidence and credible information provided to the board by the office and the public, that placing a single source drug on prior approval or restricting the drug's use will not:

(A) impede the quality of patient care in the Medicaid program; or

(B) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.

(2) Meet to review a formulary or a restriction on a single source drug after the office provides at least ~~thirty (30)~~ **fifteen (15)** days notification to the public that the board will review the formulary or restriction on a single source drug at a particular board meeting. The notification shall contain the following information:

(A) A statement of the date, time, and place at which the board meeting will be convened.

(B) A general description of the subject matter of the board meeting.

(C) An explanation of how a copy of the formulary to be discussed at the meeting may be obtained.

The board shall meet to review the formulary or the restriction on a single source drug at least ~~thirty (30)~~ **fifteen (15)** days but not more than sixty (60) days after the notification.

(3) Ensure that:

(A) there is access to at least two (2) alternative drugs within each therapeutic classification, if available, on the formulary; and

(B) a process is in place through which a Medicaid recipient has access to medically necessary drugs.

(4) Reconsider the drug's removal from its restricted status or from prior approval not later than six (6) months after the single source drug is placed on prior approval or restricted in its use.

(5) Ensure that the program provides either telephone or FAX approval or denial Monday through Friday, twenty-four (24) hours a day. The office must provide the approval or denial within twenty-four (24) hours after receipt of a prior approval request. The program must provide for the dispensing of at least a seventy-two (72) hour supply of the drug in an emergency situation or on weekends.

(6) Ensure that any prior approval program or restriction on the use of a single source drug is not applied to prevent acceptable medical use for appropriate off-label indications.

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(c) (b) The board shall advise the office on the implementation of any program to restrict the use of brand name multisource drugs.

(d) (c) The board shall consider:

- (1) health economic data;
- (2) cost data; and
- (3) the use of formularies in the non-Medicaid markets;

in developing its recommendations to the office.

SECTION 21. IC 12-15-35-43.5 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 43.5. The board, the therapeutics committee, or the office may not release proprietary or confidential information obtained as part of the development, implementation, or maintenance of a preferred drug list under this chapter.**

SECTION 22. IC 12-15-35-48 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 48. (a) The board shall review the prescription drug program of a managed care organization that participates in the state's risk-based managed care program at least one (1) time per year. The board's review of a prescription drug program must include the following:**

- (1) An analysis of the single source drugs requiring prior authorization, including the number of drugs requiring prior authorization in comparison to other managed care organizations' prescription drug programs that participate in the state's Medicaid program.
- (2) A determination and analysis of the number and the type of drugs subject to a restriction.
- (3) A review of the rationale for:
 - (A) the prior authorization of a drug described in subdivision (1); and
 - (B) a restriction on a drug.
- (4) A review of the number of requests a managed care organization received for prior authorization, including the number of times prior authorization was approved and the number of times prior authorization was disapproved.
- (5) A review of:
 - (A) patient and provider satisfaction survey reports; and
 - (B) pharmacy-related grievance data for a twelve (12) month period.

(b) A managed care organization described in subsection (a) shall provide the board with the information necessary for the

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board to conduct its review under subsection (a).

(c) The board shall report to the select joint commission on Medicaid oversight established by IC 2-5-26-3 at least one (1) time per year on the board's review under subsection (a).

SECTION 23. IC 12-15-35.5-2.5 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 2.5. As used in this chapter, "unrestricted access" means the ability of a recipient to obtain a prescribed drug without being subject to limits or preferences imposed by the office or the board for the purpose of cost savings except as provided under IC 12-15-35-8 and section 7 of this chapter.**

SECTION 24. IC 12-15-35.5-4, AS ADDED BY HEA 1233-2002, SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]:

Sec. 4. Prior authorization requirements developed under this chapter must:

- (1) comply with all applicable state and federal laws, including the provisions of 405 IAC 5-3 and 42 U.S.C. 1396r-8(d)(5); and
- (2) provide that the prior authorization number assigned to an approved request be included on the prescription or drug order:
 - (A) issued by the prescribing ~~physician~~; **practitioner**; or
 - (B) if the prescription is transmitted orally, relayed to the dispensing pharmacist by the prescribing ~~physician~~; **practitioner**.

SECTION 25. IC 12-17.6-3-3, AS ADDED BY P.L.273-1999, SECTION 177, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: Sec. 3. (a) Subject to subsection (b), a child who is eligible for the program shall receive services from the program until the earlier of the following:

- (1) ~~The end of a period of twelve (12) consecutive months following the determination of the child's eligibility for the program.~~ **The child becomes financially ineligible.**
- (2) The child becomes nineteen (19) years of age.

(b) Subsection (a) applies only if the child and the child's family comply with enrollment requirements.

SECTION 26. IC 12-17.6-4-8, AS ADDED BY P.L.291-2001, SECTION 158, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 8. (a) The office shall require the use of generic drugs in the program.

(b) The office shall use the preferred drug list implemented under IC 12-15-35-28.7.



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SECTION 27. IC 12-17.6-4-10 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 10. The office may not limit the number of brand name prescription drugs a recipient may receive under the program.**

SECTION 28. IC 25-1-9-6.8 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: **Sec. 6.8. (a) This section applies to a practitioner who is:**

- (1) licensed to practice medicine or osteopathic medicine under IC 25-22.5; or**
- (2) an advanced practice nurse granted prescriptive authority under IC 25-23, and whose practice agreement with a collaborating physician reflects the conditions specified in subsection (b).**

(b) Before prescribing a stimulant medication for a child for the treatment of attention deficit disorder or attention deficit hyperactivity disorder, a practitioner described in subsection (a) shall follow the most recent guidelines adopted by the American Academy of Pediatrics or the American Academy of Child and Adolescent Psychiatry for the diagnosis and evaluation of a child with attention deficit disorder or attention deficit hyperactivity disorder.

SECTION 29. IC 27-8-30 IS ADDED TO THE INDIANA CODE AS A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]:

Chapter 30. Specific Accident and Sickness Insurance Reporting Requirements

Sec. 1. As used in this chapter, "accident and sickness insurance policy" means a policy that:

- (1) provides the kinds of coverage described in Class 1(b) or Class 2(a) of IC 27-1-5-1; and**
- (2) includes a prescription drug benefit.**

Sec. 2. As used in this chapter, "covered individual" means an individual who is covered under an accident and sickness insurance policy.

Sec. 3. An insurer that issues an accident and sickness insurance policy may report to the drug utilization review board established by IC 12-15-35-19 the number of covered individuals who are:

- (1) less than eighteen (18) years of age; and**
- (2) prescribed a stimulant medication approved by the federal Food and Drug Administration for the treatment of attention deficit disorder or attention deficit hyperactivity disorder.**

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SECTION 30. IC 27-13-42 IS ADDED TO THE INDIANA CODE AS A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]:

Chapter 42. Specific Reporting Requirements

Sec. 1. A health maintenance organization that enters into an individual contract or a group contract that provides a prescription drug benefit may report to the drug utilization review board established by IC 12-15-35-19, not later than October 1 of each calendar year, the number of enrollees who are:

- (1) less than eighteen (18) years of age; and**
- (2) prescribed a stimulant medication approved by the federal Food and Drug Administration for the treatment of attention deficit disorder or attention deficit hyperactivity disorder.**

SECTION 31. IC 35-48-2-1, AS AMENDED BY P.L.14-2000, SECTION 77, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 1. (a) The board shall administer this article and may recommend to the general assembly the addition, deletion, or rescheduling of all substances listed in the schedules in sections 4, 6, 8, 10, and 12 of this chapter by submitting a report of such recommendations to the legislative council. In making a determination regarding a substance, the board shall consider the following:

- (1) The actual or relative potential for abuse.
- (2) The scientific evidence of its pharmacological effect, if known.
- (3) The state of current scientific knowledge regarding the substance.
- (4) The history and current pattern of abuse.
- (5) The scope, duration, and significance of abuse.
- (6) The risk to public health.
- (7) The potential of the substance to produce psychic or physiological dependence liability.
- (8) Whether the substance is an immediate precursor of a substance already controlled under this article.

(b) After considering the factors enumerated in subsection (a), the board shall make findings and recommendations concerning the control of the substance if it finds the substance has a potential for abuse.

(c) If the board finds that a substance is an immediate precursor, substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.

(d) If any substance is designated or rescheduled to a more restrictive schedule as a controlled substance under federal law and

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notice is given to the board, the board shall recommend similar control of the substance under this article in the board's report to the general assembly, unless the board objects to inclusion or rescheduling. In that case, the board shall publish the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall publish its findings.

(e) If a substance is rescheduled to a less restrictive schedule or deleted as a controlled substance under federal law, the substance is rescheduled or deleted under this article. If the board objects to inclusion, rescheduling, or deletion of the substance, the board shall notify the chairman of the legislative council not more than thirty (30) days after the federal law is changed and the substance may not be rescheduled or deleted until the conclusion of the next complete session of the general assembly. The notice from the board to the chairman of the legislative council must be published.

(f) There is established a ~~fifteen (15)~~ **sixteen (16)** member controlled substances advisory committee to serve as a consultative and advising body to the board in all matters relating to the classification, reclassification, addition to, or deletion from of all substances classified as controlled substances in schedules I to IV or substances not controlled or yet to come into being. In addition, the advisory committee shall conduct hearings and make recommendations to the board regarding revocations, suspensions, and restrictions of registrations as provided in IC 35-48-3-4. All hearings shall be conducted in accordance with IC 4-21.5-3. The advisory committee shall be made up of:

- (1) two (2) physicians licensed under IC 25-22.5, one (1) to be elected by the medical licensing board of Indiana from among its members and one (1) to be appointed by the governor;
- (2) two (2) pharmacists, one (1) to be elected by the state board of pharmacy from among its members and one (1) to be appointed by the governor;
- (3) two (2) dentists, one (1) to be elected by the state board of dentistry from among its members and one (1) to be appointed by the governor;
- (4) the state toxicologist or the designee of the state toxicologist;
- (5) two (2) veterinarians, one (1) to be elected by the state board of veterinary medical examiners from among its members and one (1) to be appointed by the governor;
- (6) one (1) podiatrist to be elected by the board of podiatric medicine from among its members;
- (7) one (1) advanced practice nurse with authority to prescribe



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legend drugs as provided by IC 25-23-1-19.5 who is:

- (A) elected by the state board of nursing from among the board's members; or
- (B) if a board member does not meet the requirements under IC 25-23-1-19.5 at the time of the vacancy on the advisory committee, appointed by the governor;
- (8) the superintendent of the state police department or the superintendent's designee; ~~and~~
- (9) three (3) members appointed by the governor who have demonstrated expertise concerning controlled substances; ~~and~~
- (10) one (1) member appointed by the governor who is a psychiatrist with expertise in child and adolescent psychiatry.**

(g) All members of the advisory committee elected by a board shall serve a term of one (1) year and all members of the advisory committee appointed by the governor shall serve a term of four (4) years. Any elected or appointed member of the advisory committee, may be removed for cause by the authority electing or appointing the member. If a vacancy occurs on the advisory committee, the authority electing or appointing the vacating member shall elect or appoint a successor to serve the unexpired term of the vacating member. The board shall acquire the recommendations of the advisory committee pursuant to administration over the controlled substances to be or not to be included in schedules I to V, especially in the implementation of scheduled substances changes as provided in subsection (d).

(h) Authority to control under this section does not extend to distilled spirits, wine, or malt beverages, as those terms are defined or used in IC 7.1, or to tobacco.

(i) The board shall exclude any nonnarcotic substance from a schedule if that substance may, under the Federal Food, Drug, and Cosmetic Act or state law, be sold over the counter without a prescription.

SECTION 32. IC 12-15-2-15.7 IS REPEALED [EFFECTIVE JULY 1, 2002].

SECTION 33. [EFFECTIVE JULY 1, 2002] **(a) As used in this SECTION, "advisory committee" refers to the controlled substances advisory committee established by IC 35-48-2-1(f), as amended by this act.**

(b) The advisory committee shall review the records maintained for the previous year by the central repository for controlled substances designated by the state police department under IC 35-48-7-10 regarding the prescribing of stimulant medications approved by the federal Food and Drug Administration for the

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treatment of attention deficit disorder or attention deficit hyperactivity for children less than eighteen (18) years of age.

(c) Not later than October 1, 2002, the advisory committee shall submit a report containing information obtained under subsection (b) to the drug utilization review board established by IC 12-15-35-19.

(d) The report required under subsection (c) may not contain any information that:

- (1) may be used to identify a child for whom a stimulant medication was prescribed; or
- (2) indicates that a particular physician's prescribing of stimulant medications to a child was inappropriate.

(e) Any meeting held by the advisory committee to comply with this SECTION is not open to the public.

(f) Unless otherwise provided by law, records reviewed by the advisory committee to comply with this SECTION are not public records.

(g) The drug utilization review board shall review:

- (1) the report submitted under subsection (c);
- (2) information submitted under:
 - (A) IC 5-10-8-12, as added by this act;
 - (B) IC 27-8-30, as added by this act; and
 - (C) IC 27-13-42, as added by this act;
- (3) information submitted by the office of Medicaid policy and planning regarding the prescribing of stimulant medications approved by the federal Food and Drug Administration for the treatment of attention deficit disorder and attention deficit hyperactivity disorder for children less than eighteen (18) years of age who participate in:
 - (A) Medicaid under IC 12-15; or
 - (B) the children's health insurance program under IC 12-17.6; and
- (4) any other relevant information concerning the prescribing of stimulant medications approved by the federal Food and Drug Administration for the treatment of attention deficit disorder or attention deficit hyperactivity for children less than eighteen (18) years of age.

(h) Before December 31, 2002, the drug utilization review board shall submit a report analyzing the information reviewed under subsection (g) to the following:

- (1) The select joint commission on Medicaid oversight established by IC 2-5-26-3.

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- (2) The legislative council.
- (3) The medical licensing board of Indiana established by IC 25-22.5-2-1.
- (i) The report required under subsection (h) must include the following:
 - (1) A comparison of the percentage of children receiving prescriptions for stimulant medications who are:
 - (A) participating in Medicaid (IC 12-15) or the children's health insurance program (IC 12-17.6); and
 - (B) not participating in a program described in clause (A).
 - (2) Scientifically determined estimates of the prevalence of major disorders in children who are treated with stimulant medications.
 - (3) A statement by the advisory committee regarding whether the information provided under subdivisions (1) and (2) indicates that stimulant medications are being disproportionately prescribed for children described in subdivision (1)(A).
 - (4) Identification of any pattern of prescribing of stimulant medications for children contrary to the most recent guidelines adopted by the American Academy of Pediatrics and the American Academy of Child and Adolescent Psychiatry.
- (j) This SECTION expires December 31, 2002.

SECTION 34. [EFFECTIVE UPON PASSAGE] (a) The governor shall appoint a psychiatrist with expertise in child and adolescent psychiatry as an additional member of the controlled substances advisory committee under IC 35-48-2-1, as amended by this act, before July 1, 2002.

(b) This SECTION expires July 1, 2002.

SECTION 35. [EFFECTIVE DECEMBER 30, 2001 (RETROACTIVE)]: (a) The Indiana prescription drug advisory committee is established to:

- (1) study pharmacy benefit programs and proposals, including programs and proposals in other states;
- (2) make initial and ongoing recommendations to the governor for programs that address the pharmaceutical costs of low-income senior citizens; and
- (3) review and approve changes to a prescription drug program that is established or implemented under a Medicaid waiver that uses money from the Indiana prescription drug account established under IC 4-12-8-2.



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(b) The committee consists of eleven (11) members appointed by the governor and four (4) legislative members. Members serving on the committee established by P.L.291-2001, SECTION 81, before its expiration on December 31, 2001, continue to serve. The term of each member expires December 31, 2005. The members of the committee appointed by the governor are as follows:

- (1) A physician with a specialty in geriatrics.
- (2) A pharmacist.
- (3) A person with expertise in health plan administration.
- (4) A representative of an area agency on aging.
- (5) A consumer representative from a senior citizen advocacy organization.
- (6) A person with expertise in and knowledge of the federal Medicare program.
- (7) A health care economist.
- (8) A person representing a pharmaceutical research and manufacturing association.
- (9) Three (3) other members as appointed by the governor.

The four (4) legislative members shall serve as nonvoting members. The speaker of the house of representatives and the president pro tempore of the senate shall each appoint two (2) legislative members, who may not be from the same political party, to serve on the committee.

(c) The governor shall designate a member to serve as chairperson. A vacancy with respect to a member shall be filled in the same manner as the original appointment. Each member is entitled to reimbursement for traveling expenses and other expenses actually incurred in connection with the member's duties. The expenses of the committee shall be paid from the Indiana prescription drug account created by IC 4-12-8. The office of the secretary of family and social services shall provide staff for the committee. The committee is a public agency for purposes of IC 5-14-1.5 and IC 5-14-3. The committee is a governing body for purposes of IC 5-14-1.5.

(d) Not later than September 1, 2004, the committee shall make program design recommendations to the governor and the family and social services administration concerning the following:

- (1) Eligibility criteria, including the desirability of incorporating an income factor based on the federal poverty level.
- (2) Benefit structure.
- (3) Cost-sharing requirements, including whether the

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program should include a requirement for copayments or premium payments.

(4) Marketing and outreach strategies.

(5) Administrative structure and delivery systems.

(6) Evaluation.

(e) The recommendations shall address the following:

(1) Cost-effectiveness of program design.

(2) Coordination with existing pharmaceutical assistance programs.

(3) Strategies to minimize crowd-out of private insurance.

(4) Reasonable balance between maximum eligibility levels and maximum benefit levels.

(5) Feasibility of a health care subsidy program where the amount of the subsidy is based on income.

(6) Advisability of entering into contracts with health insurance companies to administer the program.

(f) The committee may not recommend the use of funds from the Indiana prescription drug account for a state prescription drug benefit for low-income senior citizens if there is a federal statute or program, other than a federal Medicaid waiver, providing a similar prescription drug benefit for the benefit of low-income senior citizens.

(g) This SECTION expires December 31, 2005.

SECTION 36. [EFFECTIVE UPON PASSAGE] (a) As used in this SECTION, "office" refers to the office of Medicaid policy and planning.

(b) The office shall develop a federal Medicaid waiver application under which a prescription drug program may be established or implemented to provide access to prescription drugs for low-income senior citizens.

(c) Before the office may submit an application for a federal Medicaid waiver that will have an effect on the Indiana prescription drug program established under IC 12-10-16, the following must occur:

(1) The office shall submit the proposed Medicaid waiver to the prescription drug advisory committee established under this act.

(2) The prescription drug advisory committee must review, allow public comment, and approve the proposed Medicaid waiver.

(d) A prescription drug program established or implemented by the office or a contractor of the office under this SECTION may

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only limit access to prescription drugs for prescription drug program recipients to the extent that restrictions are in place in the Medicaid program on the date of enactment of this act.

(e) Changes to a prescription drug program that:

(1) is established or implemented by the office or a contractor of the office under this SECTION; and

(2) uses money from the Indiana prescription drug account established under IC 4-12-8-2;

must be approved by the prescription drug advisory committee established under this act.

(f) Before July 1, 2002, the office shall apply to the United States Department of Health and Human Services for approval of any waiver necessary under the federal Medicaid program to provide access to prescription drugs for low income senior citizens.

(g) A Medicaid waiver developed under this SECTION must limit a prescription drug program's state expenditures to funding appropriated to the Indiana prescription drug account established under IC 4-12-8-2 from the Indiana tobacco master settlement agreement fund.

(h) The office may not implement a waiver under this SECTION until the office files an affidavit with the governor attesting that the federal waiver applied for under this SECTION is in effect. The office shall file the affidavit under this subsection not later than five (5) days after the office is notified that the waiver is approved.

(i) If the office receives a waiver under this SECTION from the United States Department of Health and Human Services and the governor receives the affidavit filed under subsection (f), the office shall implement the waiver not more than sixty (60) days after the governor receives the affidavit.

SECTION 37. [EFFECTIVE UPON PASSAGE] (a) There is appropriated from the Indiana tobacco master settlement agreement fund (IC 4-12-1-14.3) fifteen million five hundred sixteen thousand six hundred eighteen dollars (\$15,516,618) to the Indiana prescription drug account established under IC 4-12-8-2. The budget agency shall allot the money appropriated under this subsection for the Indiana prescription drug account.

(b) Notwithstanding IC 4-12-1-14.3, the amount appropriated under subsection (a) is the remainder of the amount appropriated under P.L.21-2000, SECTION 12 for the Indiana prescription drug program that was not placed in the Indiana prescription drug account and does not count against the maximum amount of expenditures, transfers, or distributions that may be made from

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the Indiana tobacco master settlement agreement fund during the state fiscal year.

(c) This SECTION expires July 1, 2004.

SECTION 38. [EFFECTIVE UPON PASSAGE] (a) As used in this SECTION, "office" refers to the office of the secretary of family and social services.

(b) As used in this SECTION, "point of sale system" means a system that uses an electronic hardware device that is:

- (1) operated by a pharmacist on behalf of the office; and
- (2) capable of:
 - (A) reading information on a card that is issued by the office; and
 - (B) providing an immediate prescription drug benefit to the eligible recipient.

(c) Before July 1, 2002, the office shall establish and implement a point of sale system for the Indiana prescription drug program established under IC 12-10-16.

(d) This SECTION expires July 1, 2002.

SECTION 39. [EFFECTIVE JULY 1, 2002] (a) As used in this SECTION, "office" refers to the office of Medicaid policy and planning established under IC 12-8-6-1.

(b) Before September 1, 2002, the office shall apply to the United States Department of Health and Human Services to do the following:

- (1) Amend the state's waiver under 42 U.S.C. 1396n(b)(1) to include the aged, blind, and disabled in the managed care program under IC 12-15-12.
- (2) Amend the state Medicaid plan in accordance with this act.

(c) The office may not implement the amendments under subsection (b) until the office files an affidavit with the governor attesting that the amendments applied for under this SECTION have been approved. The office shall file the affidavit under this subsection not later than five (5) days after the office is notified that the amendments are approved.

(d) If the United States Department of Health and Human Services approves the amendments applied for under this SECTION and the governor receives the affidavit filed under subsection (c), the office shall implement the amendments not more than sixty (60) days after the governor receives the affidavit.

(e) The office may adopt rules under IC 4-22-2 to implement this SECTION.



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(f) This SECTION expires December 31, 2008.

SECTION 40. [EFFECTIVE UPON PASSAGE] The chairperson shall make the appointments required under IC 12-15-35-20.5, as added by this act, not more than thirty (30) days after the effective date of this act.

SECTION 41. [EFFECTIVE UPON PASSAGE] (a) As used in this SECTION, "committee" refers to the therapeutics committee established by IC 12-15-35-20.5, as added by this act.

(b) The initial terms of office for the members of the committee are as follows:

(1) Of the members appointed under IC 12-15-35-20.5(c)(1), as added by this act:

(A) one (1) member shall be appointed for a term of one (1) year;

(B) two (2) members shall be appointed for a term of two (2) years; and

(C) two (2) members shall be appointed for a term of three (3) years.

(2) Of the members appointed under IC 12-15-35-20.5(c)(2), as added by this act:

(A) one (1) member shall be appointed for a term of two (2) years; and

(B) one (1) member shall be appointed for a term of three (3) years.

(c) This SECTION expires December 31, 2003.

SECTION 42. An emergency is declared for this act.

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President of the Senate

President Pro Tempore

Speaker of the House of Representatives

Approved: _____

Governor of the State of Indiana

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